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January 11, 2021

VIA ECF

Honorable Claire C. Cecchi, U.S.D.J.
United States District Court
District of New Jersey
50 Walnut Street
Newark, NJ 07101

Re: *In re Biogen '755 Patent Litigation,* No. 2:10-cv-02734-CCC-MF

Dear Judge Cecchi:

Further to our letter of January 4, 2021 [ECF No. 1112], Biogen respectfully submits this letter in response to the letter and proposed Final Judgment that Defendants EMD Serono, Inc., and Pfizer Inc. (collectively, "Serono") submitted on December 29, 2020 [ECF Nos. 1110, 1111], and in response to the letter submitted by Defendant Bayer Healthcare Pharmaceuticals Inc. ("Bayer") on January 8, 2021 [ECF No. 1114] also requesting entry of final judgment. Biogen respectfully requests that final judgment not be entered at this time and that the Court schedule a status conference in six months.

Entry of final judgment at this time is premature for two reasons. First, the time for Biogen to file a petition for writ of certiorari to the United States Supreme Court seeking reversal of the Federal Circuit's decision does not expire until May 18, 2021, absent any extensions of time. Accordingly, entry of judgement prior to May 18 is unnecessary and inefficient. *Cf. Amado v. Microsoft Corp*., 517 F.3d 1353 (Fed. Cir. 2008) (affirming extension of stay in judgment through resolution of petition for certiorari).

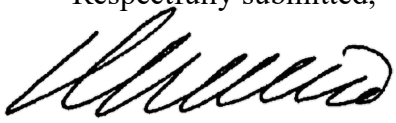
Second, there are pending proceedings in the U.S. Patent and Trademark Office ("Patent Office") that may result in the issuance of new claims that would render irrelevant the Federal Circuit's invalidity determination. Specifically, in December 2019 Bayer filed a request for *ex parte* reexamination of the patent in suit, U.S. Patent No. 7,588,755 ("the '755 Patent"). The Patent Office instituted a reexamination proceeding and on December 10, 2020, issued an office action (a non-final decision on patentability) rejecting claim 1 on the same basis on which the Federal Circuit held the '755 Patent invalid. As permitted in a reexamination proceeding, Biogen responded on December 23, 2020, proposing seventeen new claims (claims 4–20) that addressed, *inter alia*, the Federal Circuit's decision. The proposed new claims, a copy of which is attached, distinguish the method of the '755 Patent from the use of native or natural interferon beta in the prior art and thus would not implicate the Federal Circuit's invalidity determination. In particular,

all of the new claims explicitly require a "recombinant, biologically active folded protein" and several of them in addition require that the protein "has glycosylation that is not identical to that of authentic human interferon beta." This Court ruled based on the evidence presented at trial that no reasonable jury could have concluded that recombinant interferon beta produced in a non-human host cell is the same as authentic or natural human interferon beta, at least because it differs in glycosylation. [ECF Nos. 1043 (sealed), 1059 (unsealed).] The Federal Circuit did not overturn that finding but instead construed the claims to refer only to the amino acid sequence of the protein, and not to require a biologically active folded protein or a particular glycosylation pattern. The new claims, if granted, would explicitly require these elements and thus would not be deemed invalid under the Federal Circuit's decision.

Biogen expects that the Patent Office will issue a further action in the first quarter of 2021; if the new claims are determined to be patentable they will progress to issuance several weeks after that. If the new claims are issued by the Patent Office, Biogen will assert them against both Serono and Bayer. Given the possibility that these claims will issue notwithstanding the Federal Circuit decision, Biogen respectfully submits that it would be more efficient to wait until the reexamination proceedings are completed, and then consider whether the case should proceed. *Cf. Gould v. Control Laser Corp*., 705 F.2d 1340 (Fed. Cir. 1983) (affirming a stay of proceedings pending conclusion of a reexamination before the Patent Office); *SHFL Entertainment, Inc. v. DigiDeal Corp*., 729 F. App'x 931, 935–36 (Fed. Cir. 2018) (unpublished) (reversing the district court's holding that the patent infringement action was moot when the asserted claims were cancelled in reexamination because the district court failed to consider the new or amended claims that emerged from the reexaminations and whether such claims may be asserted against pre-reexamination infringing activities). This Court is deeply familiar with all of the issues regarding the '755 Patent and, Biogen submits, if there is to be further litigation on the patent it would make sense for that to occur as part of the current actions. Further, there is no prejudice to Serono or Bayer in waiting no more than a few additional months to determine whether this case will go forward.

For the foregoing reasons, Biogen respectfully requests that rather than enter judgment as Serono and Bayer request, the Court schedule a status conference in six months for an update on the status of any Supreme Court proceedings or Patent Office proceedings. Thank you for your consideration of this submission.

Respectfully submitted,



Kevin H. Marino

Encl.

cc: All counsel of record

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Control No.	: 90/014,423	Art Unit	: 3991
Patent No.	: 7,588,755	Examiner	: Padmashri Ponnaluri
Filed	: December 20, 2019	Conf. No.	: 1041
Customer No.	: 06449	Atty. No.	: 2790-229

Title: DNA SEQUENCES, RECOMBINANT DNA MOLECULES AND PROCESSES FOR PRODUCING HUMAN FIBROBLAST INTERFERON-LIKE POLYPEPTIDES

Mail Stop *Ex Parte* Reexam
Central Reexamination Unit
Commissioner for Patents
United States Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Patent Owner, Biogen Inc., respectfully submits this communication in response to the non-final Office Action mailed December 10, 2020 (the "Office Action") in the above-referenced *ex parte* reexamination. This response is timely filed on December 23, 2020, which is before the February 10, 2021 deadline set by the Office Action.

Amendments to the Claims begin on page **1** of this paper.

Remarks begin on page **6** of this paper.

I. AMENDMENTS TO THE CLAIMS

Pursuant to 37 CFR § 1.530(d) and MPEP § 2250(IV)(D), please insert new claims 4 - 20 as follows:

4. (New) A method for immunomodulation or treating a viral condition, a viral disease, cancers or tumors comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of a composition comprising:

a recombinant, biologically active, folded protein produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group consisting of:

(a) DNA sequences which are capable of hybridizing to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793) under hybridizing conditions of 0.75 M NaCl at 68° C. and washing conditions of 0.3 M NaCl at 68° C., and which code for a protein displaying antiviral activity, and (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);

said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

5. (New) The method of claim 4, wherein the recombinant, biologically active, folded protein has glycosylation that is not identical to that of authentic human interferon beta (HuIFN-β) protein.

6. (New) The method of claim 4, wherein the non-human host is a bacterial host.

7. (New) The method of claim 4, wherein the non-human host is *E. coli*.

8. (New) The method of claim 4, wherein the recombinant, biologically active, folded protein is not glycosylated.

9. (New) The method of Claim 4 in which the recombinant DNA molecule comprises the contiguous nucleotide coding sequence of HFIF3 that encodes fibroblast interferon in the 5' to 3' direction.

10. (New) The method of Claim 5 in which the recombinant DNA molecule comprises the contiguous nucleotide coding sequence of HFIF3 that encodes fibroblast interferon in the 5' to 3' direction.

11. (New) The method of Claim 8 in which the recombinant DNA molecule comprises the contiguous nucleotide coding sequence of HFIF3 that encodes fibroblast interferon in the 5' to 3' direction.

12. (New) A method for immunomodulation or treating a viral condition, a viral disease, cancers or tumors comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of a composition comprising:

a recombinant, biologically active, folded protein having glycosylation that is not identical to that of authentic HuIFN-β protein, said recombinant protein produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group consisting of:

(a) DNA sequences which are capable of hybridizing to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793) under hybridizing conditions of 0.75 M NaCl at 68° C. and washing conditions of 0.3 M NaCl at 68° C., and which code for a protein displaying antiviral activity, and (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);

said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

13. (New) A method for immunomodulation or treating a viral condition, a viral disease, cancers or tumors comprising the step of administering to a patient in need of such treatment a therapeutically effective amount of a composition comprising:

a recombinant, biologically active, folded, non-glycosylated protein produced by a non-human host transformed by a recombinant DNA molecule comprising a DNA sequence selected from the group consisting of:

(a) DNA sequences which are capable of hybridizing to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793) under hybridizing conditions of 0.75 M NaCl at 68° C. and washing conditions of 0.3 M NaCl at 68° C., and which code for a protein displaying antiviral activity, and (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a);

said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule.

14. (New) The method of claim 13, wherein the non-human host is *E. coli*.

15. (New) The method of Claim 14 in which the recombinant DNA molecule comprises the contiguous nucleotide coding sequence of HFIF3 that encodes fibroblast interferon in the 5' to 3' direction.

16. (New) The method of claim 4, wherein said protein comprises the amino acid sequence:

Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn.

17. (New) The method of claim 5, wherein said protein comprises the amino acid sequence: Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn.

18. (New) The method of claim 8, wherein said protein comprises the amino acid sequence: Asp-Ala-Ala-Leu-Thr-Ile-Tyr-Glu-Met-Leu-Gln-Asn-Ile-Phe-Ala-Ile-Phe-Arg-Gln-Asp-Ser-Ser-Ser-Thr-Gly-Trp-Asn-Glu-Thr-Ile-Val-Glu-Asn-Leu-Leu-Ala-Asn-Val-Tyr-His-Gln-Ile-Asn-His-Leu-Lys-Thr-Val-Leu-Glu-Glu-Lys-Leu-Glu-Lys-Glu-Asp-Phe-Thr-Arg-Gly-Lys-Leu-Met-Ser-Ser-Leu-His-Leu-Lys-Arg-Tyr-Tyr-Gly-Arg-Ile-Leu-His-Tyr-Leu-Lys-Ala-Lys-Glu-Tyr-Ser-His-Cys-Ala-Trp-Thr-Ile-Val-Arg-Val-Glu-Ile-Leu-Arg-Asn-Phe-Tyr-Phe-Ile-Asn-Arg-Leu-Thr-Gly-Tyr-Leu-Arg-Asn.

19. (New) The method of claim 1, wherein the polypeptide is modified by its interaction with in vivo enzymes of the non-human host.

20. (New) The method of claim 19, wherein the polypeptide is modified by glycosylation by the non-human host.

VIII. CONCLUSION

For all the foregoing reasons and those stated in Biogen's Reply to Office Action filed August 3, 2020, claim 1 of the '755 patent remains patentable and new claims –4–20 are patentable. Biogen thus respectfully requests that the Office proceed to a Notice of Intent to Issue Reexamination Certificate confirming the patentability of the challenged claim and allowing new claims 4–20.

Biogen submits herewith an excess claim fee for one independent claim in excess of three with this filing, pursuant to 37 CFR § 1.20(c) and MPEP § 2250.03. The Commissioner is hereby authorized to charge any additional fees that may be required regarding this response, or credit any overpayment, to Deposit Account No. 02-2135.

Respectfully submitted,
Biogen MA Inc.

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December 23, 2020

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